REMARKS

Claims 1-16 remain under active prosecution in the present application. Applicants respectfully assert that all amendments are supported by the original disclosure and do not introduce new matter. Moreover, Applicants further respectfully assert that the amendments merely clarify the scope of the claims.

Informalities

In the specification, paragraph 0001 has now been amended to correct a typographical error.

In the subject Office Action dated October 20, 2004, the Examiner has objected to Claims 1-7 because of informalities.

Claim 1 contained a mixture of letters (a) and numbers (1-4) used in the subparagraphs following the preamble. Claim 1 has now been amended to account for just letters in the subparagraphs.

The Examiner contends that claims 4 and 7 recite the same claim limitations and both depend from claim 1; claim 7 is duplicative of claim 4 and is not further limiting of the claimed invention. Claim 7 has now been amended to remove any duplicative claim coverage.

Claim Rejections • 35 USC§102

The Examiner has rejected Claims 1-16 under 35 U.S.C. 102(e), (effective filing date October 29, 1998) as being anticipated by Reiter et al (US 2004/0023316 A1).

The Examiner contends that Reiter et al discloses the instantly claimed invention directed to a method of detecting Helicobacter pylori antigen (see pages 1 and 3, respectively, [0003], and

[0020]) in a human fecal specimen (see title "stool", and page 4, [0038] "especially of human patients") the method comprising the steps of:

1) dispersing human fecal specimen in a protein based diluent "skim milk" see page 13, paragraph [154] which contains casein (see US Pat. 6,793958, Brief Summary paragraph 19, "instead of casein protein, it is possible to use skimmed milk protein"; Detailed Description test paragraph 4 "casein utilized in the present invention is preferably added as skimmed milk powder");

2) contacting the fecal specimen in the diluent with an antibody to form a complex (see page 13, [0154 "ELISA plates were coated for 1 hour at 37o in 100 ul of an mAK solution (2.5 ug antibody/ml carbonate buffer, 0. 1M, pH 9.5)"; a plurality of monoclonal antibodies were used, see Table 4, page 13; page 14, [0159 "combination" of monoclonal antibodies]);

3) exposing the complex to a second antibody that is labeled (see page 13, paragraph [0154, column 2, and Table 4]);

4) detecting (streptavidin with POD, produces a blue colored product) the amount of the labeled antibody (biotin labeled) in the complex and in turn determining the presence of H. pylori antigen in the fecal specimen (see page 13, Table 4).

As the Examiner points out, **both the first and second monoclonal antibodies specific were genus specific antibodies**, the epitopes to which they bound shown in Table 2, page 12, paragraph [0144]. The urease B subunit epitope (VGEVITR, amino acid sequence for epitope) is present in Helicobacter pylori, H.heilmannii, H. felis, H. hepaticus, H.bizzozeronii, Helicobacter

sp. TD1 and Campylobacter pylori (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific). Additionally, a second monoclonal that is a genus specific monoclonal with binding specificity for the alpha subunit of Helicobacter pylori (LPLGRNA, amino acid sequence of epitope), would also immunoreact with this epitope that is present in H. hepaticus and Campylobacter jejuni (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific).

Therefore, the Examiner contends that this reference inherently anticipates the instantly claimed invention.

The Applicants respectfully traverse this rejection. The Examiner is correct that the use of genus specific monoclonal antibodies on both sides of the assay as described in Reiter et al would pick up other species of *Helicobacter* or *Campylobacter*.

However, the very crux of the present invention is that it does NOT use genus directed antibodies on both sides of the assay but only uses such genus directed antibodies on ONE side of the assay. In order to get the benefit provided by the present invention, antigen specific polyclonal antibodies directed towards H. pylori only must be used on one side of the assay.

In the present application, the claims clearly require that the first and second antibodies are different:

(a) **ONE SIDE** of the assay requires ***genus specific monoclonal antibodies*** to *Helicobacter* or *Campylobacter*. The genus specific monoclonal antibodies used cross-react

with different species and strains of *Helicobacter* or *Campylobacter*. In this regard the genus specific monoclonal antibodies can also be referred to as "genus directed" monoclonal antibodies; and

(b) The **OTHER SIDE** of the assay requires *H. pylori* ***antigen specific polyclonal antibodies***. Two or more monoclonal *H. pylori* specific antibodies could be used as an alternative to using a polyclonal antibody.

Therefore, the Reiter et al. application does not disclose or suggest the present invention.

Furthermore, Applicants have now amended the claims to make it clear that the non-genus directed antibodies must be selected from the group consisting of polyclonal *H. pylori* antigen specific antibodies, a plurality of monoclonal *H. pylori* antigen specific antibodies and mixtures thereof wherein such antigen specific antibodies bind to *H. pylori* antigen and do not react with different species and strains of *Helicobacter* or *Campylobacter*.

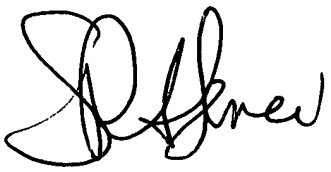
CONCLUSION

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

KENNETH JAMES KOZAK



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